NDA 10-997 DARVON (propoxyphene hydrochloride) Pulvules

NDA 16-862 DARVON-N (propoxyphene napsylate) Tablets

Opioid

Xanodyne Pharaceuticals, Inc.

One Riverfront Place

Newport, KY 41071-4563

859-371-6383

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL:

The goal of this REMS is to inform patients about the serious risks associated with the use of Darvon (propoxyphene hydrochloride) Pulvules, and Darvon-N (propoxyphene napsylate) Tablets.

II. REMS ELEMENTS:

A. Medication Guide

Xanodyne Pharmaceuticals will ensure that a Medication Guide will be dispensed with each Darvon (propoxyphene hydrochloride) and Darvon-N (propoxyphene napsylate) prescription in accordance with 21 CFR 208.24. Four Medication Guides will be shipped with each 100 count bottle. A Medication Guide will be provided with every pharmacy shelf container of Darvon (propoxyphene hydrochloride) and Darvon-N (propoxyphene napsylate) to ensure its availability for dispensing to patients. The label of each container or package of Darvon (propoxyphene hydrochloride) and Darvon-N (propoxyphene napsylate) will include a prominent instruction to authorized dispensers to provide a Medication Guide to each patient to whom the drug is dispensed.

In addition, the Medication Guide will be included with all samples and trade packets intended for direct distribution to patients.

Please see appended Medication Guide.

B. Timetable for Submission of Assessments

Xanodyne Pharmaceuticals will submit REMS assessments to FDA 18 months, 3 years, and 7 years from the date of the approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Xanodyne Pharmaceuticals will submit each assessment so that it will be received by the FDA on or before the due date.

NDA 17-722 DARVOCET-N (propoxyphene napsylate and acetaminophen) Tablets

Opioid with Non-opioid

Xanodyne Pharmaceuticals, Inc.
One Riverfront Place
Newport, KY 41071-4563
859-371-6383

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL:

The goal of this REMS is to inform patients about the serious risks associated with the use of Darvocet-N (propoxyphene napsylate and acetaminophen) Tablets.

II. REMS ELEMENTS:

A. Medication Guide

Xanodyne Pharmaceuticals will ensure that a Medication Guide will be dispensed with each Darvocet -N (propoxyphene napsylate and acetaminophen) prescription in accordance with 21 CFR 208.24. Four Medication Guides will be shipped with each 100 count bottle. A Medication Guide will be provided with every pharmacy shelf container of Darvocet -N (propoxyphene napsylate and acetaminophen) to ensure its availability for dispensing to patients. The label of each container or package of Darvocet -N (propoxyphene napsylate and acetaminophen) will include a prominent instruction to authorized dispensers to provide a Medication Guide to each patient to whom the drug is dispensed.

In addition, the Medication Guide will be included with all samples and trade packets intended for direct distribution to patients.

Please see appended Medication Guide.

B. Timetable for Submission of Assessments

Xanodyne Pharmaceuticals will submit REMS Assessments to FDA 18 months, 3 years, and 7 years from the date of the approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Xanodyne Pharmaceuticals will submit each assessment so that it will be received by the FDA on or before the due date.